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EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 05/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/659,367	CHEN ET AL.	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-70* is/are pending in the application.

4a) Of the above claim(s) *34-67,69 and 70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33 and 68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6/2/04; 2/9/04 + 12/10/03
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I claims 1-33 and 68 in the reply filed on April 7, 2006 is acknowledged. The traversal is on the ground(s) that in this application, claims of Groups I and II, while patentably distinct from each other, are directed to a similar subject matter insofar as the appliance of Group II includes the multiplicity of devices of Group I. Applicant further argues that claims of Groups I and III are related to each other as underscored by the classification of both of these groups in Class 435, though in different subclasses. Applicant also states that different classification of claims in not necessarily an indication of the distinctiveness of Group I from Groups II and III and that art relevant to the claims of Group I may be found in the class/subclass associated with Groups II and III and vice versa. This is not found persuasive because of reasons of record and because restriction requirements are set forth for reasons of patentable distinction between each independent invention so as to warrant separate classification and search. The record set forth in the previous restriction requirement clearly indicated that the delineated inventions are in fact patentably distinct each from the other or independent from the other. Further, the search for different groups requires different search terms and different search strategy that creates a burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Specification

2. The disclosure is objected to because of the following informalities: On page 26 the specification lacks a heading entitled Brief Description of the Drawings. It is recommended to amend the specification on page 26 to include the heading --Brief Description of the Drawings--.

3. Also, page 8, lines 23 and 24 in the specification is unclear because of the disclosure "10-30.000 *u*m" and "10-10.000 *u*m". It appears that applicant intends 30,000 and 10,000 respectively. Please clarify.

Appropriate correction is required.

4. The specification is also objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 20 recites "wherein the third zone comprises 1-99% of the porous material used in the first zone, second zone, third zone and fourth zone". However, the specification on page 15, lines 8 and 9 disclose the third zone constitute 1-99% of the device. Thus the specification fails to provide proper antecedent basis for claim 20 as recited.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2-33 and 68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2, line 1 the recitation "a device" is vague and indefinite. It is unclear if applicant is referring to the device of claim 1 or some other device. It is recommended to amend the claim to --the device of claim 1--. See also deficiencies found in claims 2-33 and 68.

Claim 12 is vague and indefinite because it is unclear if the porous material binds to proteins or if the immobilized anlayte or analogue binds to proteins. Does applicant intend proteins are the analytes in the sample that will be detected or does applicant intend that the porous material binds non-specifically to proteins. It is unclear what applicant intends. Please clarify.

Claim 17 provides for the use of CMO and/or HMS, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 17 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 17 is vague and indefinite because of the use of acronyms: ie CMO and HMS. Although the terms may have art-recognized meanings, it is unclear if applicant intends to claim the prior art definitions. The terms should be defined in their first instance:

Claim 18 and 19 are vague and indefinite because they fail to further limit the device of claim 1. Claims 18 and 19 appear to be directed toward the methods of making the device and do not positively recite limitations of the third zone other than the third zone has a length.

Claim 20 is vague and indefinite because it is unclear if the 1-99% of the porous material is used for each zone or material used in relation to other zones or does this percentage indicate the overlapping of the zones. Further, it is unclear how the third zone comprises 1-99% of the third zone.

Claim 27 the recitation "substantially consistent" is vague and indefinite. There is no definition provided for the term in the specification and it is unclear what is considered to be substantially consistent.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 5, 9-13, 20, 24, 25 28, 30-33 and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by Good et al (US 6,194,224).

Good et al disclose a device comprising a sample receiving zone (zone 1)(see Figures 1-3). Good et al disclose the device comprises a reagent zone (second zone) which contains labeled antibodies (non-immobilized molecule) which are specific for the analyte of interest. Good et al disclose the device comprises an area (third zone) that is

overlapped by the reagent zone and extends to a test zone. Good et al disclose that this area (third zone) is comprised of a nitrocellulose having a pore size of 200 nm to about 500 nm (col 4). Good et al disclose the device comprises a test zone (fourth zone) having immobilized anlayte (col 3 & col 4). Good et al disclose that the first zone and second zone are overlapping. Good et al disclose that the second zone and third zone are overlapping. Good et al disclose that the different zone can be comprised of different materials. Good et al disclose that the device comprises a liquid sink zone or waste pad (fifth zone) that absorbs excess liquid in the sample. Good et al disclose that the membrane can comprise latex (col 5-6). Good et al disclose that the sample receiving zone comprises a surfactant (ancillary compound) which provides better flow characteristics of the specimen (col 3 and abstract). Good et al disclose that the surfactant works especially well when the sample is a viscous sample.

With respect to the recitation "retarding the rate of migration of the sample and the non-immobilised molecule" as recited in the instant claims. Since Good et al disclose the same device and disclose the same pore size in the third zone that applicant uses, the device of Good et al would retard the rate of migration of the sample and the non-immobilised molecule. Thus, Good et al reads on the instantly recited claims.

With respect to claims 12 and 13 as instantly recited. Since Good et al disclose the same structure, materials and pore size as instantly claimed. The porous material of Good et al would bind proteins in the range as recited and would also have a capillary flow-rate as recited. Further, it is unclear what applicant intends in claim 12 (see 112 2nd above). Therefore, Good et al reads on the instantly recited claims.

With respect to claim 20 as instantly recited. Support for the recitation "the third zone comprises 1-99% of the porous material" is found on page 15, lines 8-9, but the specification refers to the third zone to area of the device. Therefore, the Examiner has interpreted this as the length of the device and a review of Good et al shows that the first, second, third and fourth zones would comprises 1-99% of the device. Thus, Good et al reads on the instantly recited claim.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 4 and 6 rejected under 35 U.S.C. 103(a) as being unpatentable over Good et al in view of Polzius et al (US 6,130,097) or Schlipfenbacher et al (US 5,160,486).

See above for the teachings of Good et al.

Good et al differs from the instant invention in failing to teach the third zone and fourth zone overlapping and the fourth zone and fifth zone overlapping.

Polzius et al teach that it is known in the art to overlap zones on a test strip to provide for fluid contact of the zones (col 4).

Schlipfenbacher et al teach that it is known in the art to overlap zone on a test strip. Schlipfenbacher et al teach that this provides for the zone to be in liquid contact with one another so that they form a liquid transport path along which a liqid flows, driven by capillary forces, from a start zone (col 1 – col 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate overlapping as taught by Polzius et al and Schlipfenbacher et al into the third, fourth and fifth zones of Good et al because both Polzius et al and Schlipfenbacher et al show that it is known in the art to overlap zones on a test strip and also show that this provides for fluid contact and a liquid transport path. Therefore, one of ordinary skill in the art would have a reasonable expectation of

success incorporating overlapping as taught by Polzius et al and Schlipfenbacher et al into the device of Good et al.

13. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Good et al in view of Davis et al (US 6,352,862).

See above for the teachings of Good et al.

Good et al differ from the instant invention in failing to teach a second labeled molecule in the second zone and its binding partner in the forth zone.

Davis et al teach the method and device for determining analytes. Davis et al teach the use of immobilized analytes or anologues and labeled reagents in the strip (col 4, line 64 – col 5, line 3). Davis et al teach the use of several labeled specific binding reagents each carrying a different label in a test strip. Davis et al disclose that this facilitates the manufacture of a multiple analyte testing device (col 4, lines 8-14). Davis et al teaches the use of multiple capture reagents col 8, line 65 – col 9, line 27). Davis et al teach that the determination of more than one analyte can have significant clinical utility.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate multiple labeled and multiple immobilized reagents as taught by Davis et al into the device of Good et al because Davis et al shows that this facilitates the manufacture of a multiple analyte testing device and also teaches that the determination of more than one analyte can have significant clinical utility. Therefore, one of ordinary skill in the art would have a reasonable expectation of

success incorporating multiple reagents as taught by Davis et al into the device of Good et al.

14. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Good et al in view of Lee et al (WO 02/04671).

See above for the teachings of Good et al.

Good et al differ from the instant invention in failing to teach a spacer molecule or the spacer molecule is bovine serum albumin (BSA).

Lee et al disclose BSA used as a spacer molecule to immobilize a capture probe to a test strip. Lee et al disclose that the use of this spacer increases the stability of the interaction between the capture probe and the target and thus improves sensitivity of the detection.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a spacer molecule such as taught by Lee et al into the device of Good et al because Lee et al shows that use of this spacer increases the stability of the interaction between the capture probe and the target and thus improves sensitivity of the detection.

15. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Good et al in view of Lee et al and further in view of Henderson et al (US 2004/0072248).

See above for the teachings of Good et al and Lee et al.

Good et at and Lee et al differ from the instant invention in failing to teach the spacer molecule and the analyte being immobilized to the fourth zone are coupled using CMO.

Henderson et al teach the use of carboxymethyloxime (CMO) conjugated to bovine serum albumin and conjugated to an oestrogen and used as a binding substance. Henderson et al disclose that this binding substance is immobilized on the surface of a test strip and used in assays.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate CMO as taught by Henderson et al into the modified device of Good et al because Henderson shows that it is known in the art to use CMO for immobilization of proteins on the surface of test strips. Therefore, one of ordinary skill in the art would have a reasonable expectation of success incorporating CMO as taught by Henderson et al into the modified device of Good et al.

16. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Good et al in view of Frushour et al (US 2003/0059951).

See above for the teachings of Good et al.

Good et al differ from the instant invention in failing to teach changing the length of the porous material used.

Frushour et al teach that the spatial separation between zones on a test strip and the flow rate characteristics of the porous solid phase material can be selected to allow adequate reaction times during which the necessary specific binding can occur, and to allow the labeled antibody in the labeled antibody zone to dissolve through the porous solid phase material (para. 0055). Therefore, Frushour et al is teaching optimizing the test strip to allow for the desired incubation time.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to change the length of the third zone of Good et al as taught by Frushour et al because Frushour et al teaches that this provides for the optimal reaction times during which the necessary specific binding can occur, and to allow the labeled antibody in the labeled antibody zone to dissolve or disperse in the liquid sample and migrate through the porous solid phase material. Further, the optimal length of the third zone relative to the other zones can be determined by routine experimentation and thus would have been obvious to one or ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation ." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

17. Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Good et al in view of Robinson et al (WO 95/16914).

See above for the teachings of Good et al.

Good et al differ from the instant invention in failing to teach the device further comprises a calibration zone.

Robinson et al disclose the use of calibration zone(s), in which a calibration reagent is immobilized and has biospecific affinity for the analyte of interest or the binding partner of interest (page 15, lines 15-24). Robinson et al also disclose a releasable reagent predeposited (abstract). Robinson et al also disclose that the device may be a flow through device such as test strip (page 5, lines 7-22). Robinson et al also disclose that the specific binding partner can be coupled to or conjugated to the calibrator (see page 17), to form a complex for detection. Robinson et al disclose that the reagents may be antigen/antibody complexes. Robinson et al disclose that the antibodies can be monoclonal antibodies. Robinson et al disclose that calibrator zones used in this manner offers means for calibrating the assay as part of the assay procedure (page 3, lines 15-16) and also provides advantages for additional compensation for various factors in the assay system which may influence the level of signal observed (page 14, lines 24-26).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the use of a calibrator zone as taught by Robinson et al into the device of Good et al because Robinson et al shows that this provides advantages for additional compensation for various factors in the assay system which may influence the level of signal observed.

18. Claims 26, 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Good et al in view of Sundrehagen (US 6,716,641).

See above for the teachings of Good et al.

Good et al differ from the instant invention in failing to specifically state that the ancillary compound decreases non specific binding and provides release of the non-immobilized molecule.

Sundrehagen discloses the use of reagents in zones on a test strip. Sundrehagen disclose that the use of these reagents prevents non-specific binding of the detector reagent and/or analyte (col 15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate reagents such as taught by Sundrehagen into the device of Good et al because Sundrehagen teaches that this provides for the prevention of non-specific binding of the detector reagent and/or analyte. Further, it is noted that a review of applicant's specification on pages 25-26 discloses the use of ancillary compounds and what the ancillary compounds provide, but the specification does not disclose a species of the ancillary compound nor provides guidance of what the ancillary compound may be. Therefore, the combination of references teach ancillary compounds the same as applicant has discloses and therefore would be capable of providing the specific characteristics as recited and thus the combination of references read on the claims.

Conclusion

19. No claims are allowed.

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Boehringer et al (US 6,924,153) disclose a device comprising a sample receiving zone, labeling zone, capture zone and absorbent zone.

Goerlach-Graw et al. (US 7,026,002) disclose a device comprising a sample application zone, a zone containing immobilized analyte or analyte analogue between the sample application zone and the detection zone; and impregnated conjugate that can be detached by liquid located in the sample application zone or downstream thereof.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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